

SEP 23 2009

K691800

Attachment III

8.0 Executive Summary

Curve Medical is requesting marketing clearance for a cannula.

Trade Name: LipoEze Laser Assisted Aspiration Cannula

Device Name: LipoEze Laser Assisted Aspiration Cannula

Common Name: Handpiece Accessory

Classification: Class II

Manufacturer/Sponsor: Curve Medical, Inc.
2621 Newton Ave South
Minneapolis, MN 55405

Registration: (awaiting number)

Consultant/Contact: MEDlcept, Inc.
200 Homer Ave
Ashland, MA 01721

Primary Contact: F. David Rothkopf
508-231-8842 x20
508-231-8861 Fax

Product Codes: GEX, Powered Laser Surgical Instrument

Device Classification: 878.4810, Powered Laser Surgical
Instrument

Classification Panel: General & Plastic Surgery

Predicates:

K933017, Sunrise Technologies Model 5030 Suction Handpiece System
878.4810, GEX, Powered Laser Surgical Instrument, Class II

K073617 Osyris: PHARAON LIPO
878.4810, GEX, Powered Laser Surgical Instrument, Class II



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 23 2009

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Curve Medical
% MEDIcept
Mr. F. David Rothkopf
President
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K091800

Trade/Device Name: LipoEze Cannula

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and
in dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: September 16, 2009

Received: September 18, 2009

Dear Mr. Rothkopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

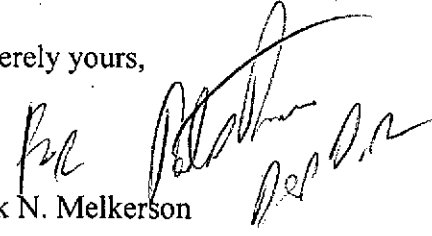
Page 2 - Mr. F. David Rothkopf

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment II

Indications for Use

510(k) Number (if known): K091800

Device Name: LipoEze Cannula

Indications for Use: The LipoEze Cannula is a suction hand piece intended for use with a 980nm laser fiberoptic delivery system during laser assisted lipolysis.

Prescription Use ☒ 21CFR 801, Subpart D **OR** Over-the-Counter Use ☐ 21CFR
801.109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE
IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. G. for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091800